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EXAMINER	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/501,162	BOSNES, MARIE	
	Examiner	Art Unit	
	Narayan K. Bhat	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 June 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) *30-32* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12 July 2007* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/13/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-32 are pending in this application.

Election/Restrictions

2. Applicant's election without traverse of group I in the reply filed on June 11, 2007 is acknowledged.

3. Claims 30-32 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on June 11, 2007.

4. Claims 1-29 are under prosecution.

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1, 5-6, 11-13, 15-17, 19, 22-24, 26 and 28-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Baer et al (WO 00/61806 published October 19, 2000, herein after Baer).

Regarding claim 1, Baer teaches a method that include contacting a sample (pg. 16, paragraph 5) with probe molecules bonded to the solid support (Fig. 1, elements # 160 and 162, pgs. 9 and 10, paragraphs 6 and 1-3) and further teaches the biotinylated nucleic acid probe molecules bound to avidin-labelled support to which nucleic acids components bind (pg. 16, paragraph 3) and antibody molecules conjugated with biotin bound to avidin-labeled support to which protein components binds (pg. 16, paragraph 4). Baer also teaches that the preferred solid supports are beads (pg. 5, lines 25-31). Binding of nucleic acid and antibody probes to solid support with avidin for capturing of biotin taught by Baer thus meets the claim limitation of plurality of distinct solid supports because the preferred bead supports would have provided multiple distinct solid supports as claimed. Teachings of Bear thus encompass nucleic acid and protein components contained in the sample become bound to the solid supports wherein the solid supports to which nucleic acids components are bound are distinct from the solid supports to which protein components are bound.

Regarding claim 5, Baer teaches that the RNA and protein are isolated from the same sample (pg. 16, paragraph 5).

Regarding claim 6, Baer teaches that the RNA is mRNA (pg. 16, paragraph 5).

Regarding claim 11, Baer teaches that the sample is a biopsy sample from a breast cancer patient (pg. 16, paragraph 5), which is a clinical or biological sample.

Regarding claim 12, Baer teaches that prior to contacting said sample with said solid supports, the sample is subjected to a cell lysis with GITC detergent buffer (pg. 11, paragraph 5) and releasing the cell contents in to buffer solution that is, a preliminary treatment step to free the nucleic acid and/or protein components from structures or entities in which they may be contained.

Regarding claim 13, Baer teaches the microdisection of a biopsy sample from a breast cancer patient to "choose cells of interest" (pg. 16, paragraph 5), i.e., prior to contacting said sample with said solid supports, the sample is subjected to a cell isolation procedure.

Regarding claim 15, Baer teaches that the cells are lysed with GITC containing buffer (pg. 11, paragraph 5), thus teaching sample is subjected to a cell lysis step prior to contacting said sample with said solid supports.

Regarding claim 16, Baer teaches an assay that includes laser capture microdisection of the biopsy sample to choose cells of interest (pg. 11, paragraph 5). Since the invtro modification is not defined in the instant specification, manipulation of sample in vitro by laser as taught be Baer meets the limitation of the said claim, namely, cell surface proteins of cells within or isolated from said sample are subjected to an in vitro modification procedure prior to the cell lysis step.

Regarding claim 17, Baer teaches that cell lysate is mixed with reagents (pg. 16, paragraph 5) and used for nucleic acid and protein isolation thus teaching that the sample is not divided at any stage of the method.

Regarding claim 19, Baer teaches that the sample is lysed and cellular contents are contacted with the probe on the solid supports simultaneously (pg. 16, paragraph 5).

Regarding claims 22 and 23, Baer teaches that the cells are lysed with GITC containing buffer, that is detergent and cell lysate is mixed with reagents (pg. 11, paragraph 5) and hybridized with multiple probe molecules on the solid support (Fig. 1, probes -elements # 160 and 162, solid support element # 110) binding to different nucleic acid target molecules (Fig. 1, elements # 170 and 172, pgs. 10 and 17, paragraphs 1 and 6) that include DNA, thus teaching DNA is isolated by binding to a solid support, in the presence of a detergent (limitation of claim 22) and simultaneously (limitation of claim 23).

Regarding claim 24, Baer teaches that probe molecules are biotinylated probe for HER-2/neu mRNA bound to avidin-labelled support to which HER2/neu mRNA binds (pg. 16, paragraph 3) thus teaching RNA is isolated using an RNA-specified capture-probe attached to a solid support.

Regarding claim 26, Baer teaches that antibody probes are conjugated with biotin bound to avidin labeled support to which protein components bind (pg. 16, paragraph 4) thus teaching protein is isolated using an appropriate binding partner/ligand attached to a binding to said solid support.

Regarding claims 28 and 29, Baer teaches that the solid supports comprise particles (pg. 3, paragraph 3, limitation of claim 28) and are magnetic particles (pg. 5, paragraph 3, limitation of claim 29).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 1, 2, 7-10, 12-14 and 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baer et al (WO 00/61806 published October 19, 2000, herein after Baer) in view of Riol et al (Analytical Biochemistry, 1999, 275, 192-201, herein after Riol).

Claims 2 and 8-10 are dependent on claim 1.

Regarding claim 1, Baer teaches a method that include contacting a sample (pg. 16, paragraph 5) with probe molecules bonded to the solid support (Fig. 1, elements # 160 and 162, pgs. 9 and 10, paragraphs 6 and 1-3) and further teaches the biotinylated

nucleic acid probe molecules bound to avidin-labelled support to which nucleic acids components bind (pg. 16, paragraph 3) and antibody molecules conjugated with biotin bound to avidin-labeled support to which protein components binds (pg. 16, paragraph 4). Baer also teaches that the preferred solid supports are beads (pg. 5, lines 25-31). Binding of nucleic acid and antibody probes to solid support with avidin for capturing of biotin taught by Baer thus meets the claim limitation of plurality of distinct solid supports because the preferred bead supports would have provided multiple distinct solid supports as claimed. Teachings of Bear thus encompass nucleic acid and protein components contained in the sample become bound to the solid supports wherein the solid supports to which nucleic acids components are bound are distinct from the solid supports to which protein components are bound.

Regarding claim 2, Baer teaches a solid support (Fig. 1, element # 110) with multiple probe molecules (Fig. 1, elements # 160 and 162) binding to different nucleic acid target molecules (Fig. 1, elements # 170 and 172, pg. 10, paragraph 1) and further teaches mixing of the cell lysate to plurality of the probes bound to solid support with assay reagents to hybridize probe molecules with the target (pg. 11, paragraph 5). Cell lysate contain both DNA and RNA molecules and hybridize to the probe molecules on the same solid support, thus meeting the limitation of the said claim.

Regarding claim 7, Baer teaches the cell lysate from a biopsy sample but silent about genomic DNA. Isolation of genomic DNA was known in the art at the time of the claimed invention as taught by Riol.

Riol teches the isolation of genomic DNA from lymphocytes (pg. 193, paragraph 2) and further teaches an optimized method isolate total DNA, RNA and protein component from limited amount of biological materials simultaneously from the same sample to enhance the understanding of genotypic and phenotypic relation ship (pg. 192, column 1).

It would be obvious to one having the ordinary skill in the art at the time the invention was made to include the total DNA, RNA and protein component from the same sample of Riol in the nucleic acid and protein isolation method of Baer with the expected benefit of using optimized method isolate total DNA, RNA and protein component from limited amount of biological materials simultaneously from the same sample to enhance the understanding of genotypic and phenotypic relation ship as taught by Riol (pg. 192, column 1).

Regarding claims 8-10, Baer teaches the isolation of HER2/neu mRNA and protein (pg. 16, paragraphs 3-5) but silent about isolation of total nucleic acid and protein component. However, isolation of total nucleic acid and protein component was known in the art at the time of the claimed invention as taught by Riol.

Riol teaches the isolation of total RNA, DNA (Fig. 5, see RNA and DNA, pg. 193, column 2, paragraph 2; limitation of claim 8) and protein component (Fig. 5, see

proteins, pg. 194, column 1; limitation of claim 10) from the same sample. The teachings of Riol isolating total RNA and DNA component from the same sample (pg. 193, column 2, paragraph 2; limitation of claim 8) thus meets the limitation of isolating total nucleic acid component (limitation of claim 9). Riol also teaches an optimized method isolate total DNA, RNA and protein component from limited amount of biological materials simultaneously from the same sample to enhance the understanding of genotypic and phenotypic relation ship (pg. 192, column 1).

It would be obvious to one having the ordinary skill in the art at the time the invention was made to include the total DNA, RNA and protein component from the same sample of Riol in the nucleic acid and protein isolation method of Baer with the expected benefit of using optimized method isolate total DNA, RNA and protein component from limited amount of biological materials simultaneously from the same sample to enhance the understanding of genotypic and phenotypic relation ship as taught by Riol (pg. 192, column 1).

Claim 14 is dependent on claim 13, which is dependent on claim 1. Teachings of Baer regarding claim 1 is described previously in this office action.

Regarding claim 13, Baer teaches the microdisection of a biopsy sample from a breast cancer patient to "choose cells of interest" (pg. 16, paragraph 5), i.e., prior to contacting said sample with said solid supports, the sample is subjected to a cell isolation procedure.

Regarding claim 14, Baer teaches the choosing the cells of interest but silent about isolation of cells from sample. However, isolation of particular cell population was known in the art at the time of the claimed invention as taught by Riol.

Riol teaches the isolation of lymphocyte population of cells from blood sample (pg. 193, column 2, paragraph 1) and further teaches that lymphocytes are better samples and easy to obtain and provide clues to human longevity (pg. 192, column 2).

It would be obvious to one having the ordinary skill in the art at the time the invention was made to include the protocol for lymphocyte isolation from blood of Riol as an alternative resource for cells in the method of Baer with the expected benefit of using lymphocytes that are better samples and easy to obtain and provide clues to human longevity as taught by Riol (pg. 192, column 2).

Claim 18 is dependent on claim 12, which is dependent on claim 1. Teachings of Baer regarding claim 1 are described previously in this office action.

Regarding claim 12, Baer teaches that prior to contacting the sample with solid supports, the sample is subjected to a cell lysis with GITC detergent buffer (pg. 11, paragraph 5) and releasing the cell contents in to buffer solution that is, a preliminary treatment step to free the nucleic acid and/or protein components from structures or entities in which they may be contained.

Regarding claim 18, Baer does not teach dividing cells. However dividing cells was known in the art at the time of the claimed invention as taught by Riol.

Riol teaches the isolation of lymphocyte population of cells from blood sample and further teaches lymphocytes are used for cell count for viability (pg. 193, column 2, paragraph 1) thus teaching sample is divided after cell isolation. It would be obvious to one having the ordinary skill in the art at the time the invention was made to divide sample for quality control test with the expected benefit of maintaining high quality of lymphocyte preparation from different blood samples as taught by Riol (pg. 192, column 2) thus providing an alternative resource of excellent quality of cells in the method of nucleic acid and protein isolation of Baer.

Claim 20 is dependent on claim 19, which is dependent on claim 1. Teachings of Baer regarding claim 1 are described previously in this office action.

Regarding claim 19, Baer teaches that the said sample is lysed and cellular contents are contacted with the probe on the solid supports simultaneously (pg. 11, paragraph 5).

Regarding claim 20, Baer does not teach sequential isolation of RNA and DNA and protein. However sequential isolation of RNA and DNA and protein was known in the art at the time of the claimed invention as taught by Riol.

Riol teaches the that the in a first step RNA is isolated from lymphocyte sample, in a second step DNA is isolated from said sample and in a third step, protein is isolated from said sample (pgs. 193 and 194, column 2, paragraph 3 and column 1).

It would be obvious to one having the ordinary skill in the art at the time the invention was made to sequentially process RNA first and then DNA and protein as

taught by Riol that following organic phase separation, RNA is in the aqueous phase, DNA in the inter phase and proteins in the organic phase (pg. 193, column 2, paragraph 2) with the expected benefit of utilizing precious biological limited samples to enhance the understanding of genotypic and phenotypic relationship as taught by Riol (pg. 192, column 1) thus improving the assay utilities of the nucleic acid protein isolation method of Baer.

9. Claims 1, 4, 21, 24 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baer et al (WO 00/61806 published October 19, 2000, herein after Baer) in view of Hornes et al (USPN 5,512,439 issued April 30, 1996).

Claim 4 is dependent on claim 1. Teachings of Baer regarding claim 1 are described previously in this office action.

Regarding claim 4, Baer teaches the isolation of RNA on a solid support but does not specifically teach DNA and RNA bound to different solid supports in separate steps. However different solid supports for DNA and RNA isolation was known in the art at the time of the claimed invention as taught by Hornes et al.

Hornes et al teaches a magnetic bead support specfic for the the isolation of mRNA and ssDNA from a sample (column 12, lines 5-12). Hornes et al further teaches that the magnetic bead carrying carboxyl groups have very low non-specific binding of DNA and RNA(column 4, lines 29-31).

It would be obvious to one having the ordinary skill in the art at the time the invention was made to include the magnetic bead carrying surface carboxyl group of

Hornes et al for the magnetic bead of Baer with the expected benefit of having very low non-specific binding of DNA and RNA as taught by Hornes et al (column 4, lines 29-31) thus providing additional utilities for the assay of Baer for isolating nucleic acids.

Claim 21 is dependent on claim 1. Teachings of Baer regarding claim 1 are described previously in this office action.

Regarding claim 21, Baer does not teach a support carrying surface carboxyl groups. However DNA isolation on a support carrying surface carboxyl groups was known in the art at the time of the claimed invention as taught by Hornes et al.

Hornes et al teaches a magnetic bead support carrying surface carboxyl groups (column 4, lines 29-31) and further teaches the isolation of ssDNA from a sample (column 12, lines 5-6). Hornes et al further teaches that the magnetic bead carrying carboxyl groups have very low non-specific binding of DNA (column 4, lines 29-31).

It would be obvious to one having the ordinary skill in the art at the time the invention was made to include the magnetic bead carrying surface carboxyl group of Hornes et al for the magnetic bead of Baer with the expected benefit of having very low non-specific binding of DNA as taught by Hornes et al (column 4, lines 29-31) thus providing additional utilities for the assay of Baer for isolating nucleic acids.

Claim 25 is dependent on claim 24, which is dependent on claim 1. Teachings of Baer regarding claim 1 are described previously in this office action.

Regarding claim 24, Baer teaches that probe molecules are biotinylated probe for HER-2/neu mRNA bound to avidin-labelled support to which HER2/neu mRNA binds (pg. 16, paragraph 3) thus teaching RNA is isolated using an RNA-specified capture-probe attached to a solid support.

Regarding claim 25, Baer teaches probe molecules specific for target molecules (pg. 9, paragraph 5) but silent about dT oligonucleotide on a solid support. However dT oligonucleotide on a solid support was known in the art at the time of the claimed invention as taught by Hornes et al.

Hornes et al teaches a magnetic bead coated with dT oligonucleotide (column 15, lines 41-47) and further teaches the isolation of mRNA from cell lysate (column 17, lines 51-67).

It would be obvious to one having the ordinary skill in the art at the time the invention was made to include the magnetic bead carrying dT oligonucleotide of Hornes et al for the magnetic bead of Baer with the expected benefit of isolating polyA RNA from cell lysate as taught by Hornes et al (column 4, lines 29-31) thus providing additional utilities for the assay of Baer for isolating total mRNA.

10. Claims 1 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baer et al (WO 00/61806 published October 19, 2000, herein after Baer) in view of Noble et al (USPN 5,084,169 issued January 28, 1992).

Claim 27 is dependent on claim 1. Teachings of Baer regarding claim 1 are described previously in this office action.

Regarding claim 27, Baer teaches the isolation and detection of HER/neu2 protein on an avidin –biotinylated antibody specific binding affinity for HER2/neu protein (pg. 16, paragraphs 4-5) but does not teach a support carrying surface capable of effecting a chromatographic interaction. However support carrying surface capable of effecting a chromatographic interaction was known in the art at the time of the claimed invention as taught by Noble et al.

Noble et al teaches a method for separating proteins from lysed cell mixture utilizing magnetizable ion exchnge particles (Fig. 1, columns 3 and 4, lines 17-67 and 1-25) thus teaching 38membranemagnetizable porous bead support carrying surface carboxyl groups (column 4, lines 29-31) protein is isolated using a solid support having a surface capable of effecting a chromatographic interaction. Noble et al also teaches the lysate clarification is not necessary and thus increasing the protein yield (column 3, lines 45-54).

It would be obvious to one having the ordinary skill in the art at the time the invention was made to include the support carrying surface capable of effecting a chromatographic interaction of Noble et al as an alternative means for the avidin-biotin support of Baer with the expected benefit of using the lysate without clarification and increasing the protein yield (column 3, lines 45-54) thus improving the yield of proteins in the protein method of Baer.

11. Claims 1, 3, 6-12, 17-20, 22-24, 26 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ibrahim (USPN 6,919,200 filed November 22, 1999) in view of Riol et al (Analytical Biochemistry, 1999, 275, 192-201, herein after Riol).

Regarding claim 1, Ibrahim teaches a method of isolating nucleic acid and protein from each other in a sample, said method comprising contacting said sample with a sample collection assembly (Fig. 1, element # 4) with a series of microstructures (Fig. 1, element # 13, column4, lines 29-44) and further teaches that said microstructures contains microparticles coated with a target specific oligonucleotides, peptides or cell receptors to capture a target DNA, RNA and proteins (column 5, lines 25-33). Sample collection assembly of Ibrahim is the solid support of the instant claim. Ibrahim also teaches the isolation and purification of nucleic acids or proteins (column 6, lines 51-54) thus teaching the use of different sample collection assembly, i.e., a plurality of solid supports. Teachings of Ibrahim provides a method wherein nucleic acid and protein components contained in a sample become bound to the solid supports wherein the solid supports to which nucleic acids components are bound are distinct from the solid supports to which protein components are bound.

Ibrahim does not teach isolation of nucleic acids and proteins from the same sample. However isolation of nucleic acids and proteins from the same sample was known in the art at the time of the claimed invention as taught by Riol.
Riol teaches the isolation of total RNA and DNA (Fig. 5, see RNA and DNA, pg. 193, column 2, paragraph 2) and protein component (Fig. 5, see proteins, pg. 194, column 1) from the same sample. Riol also teaches an optimized method isolate total DNA, RNA

and protein component from limited amount of biological materials simultaneously from the same sample to enhance the understanding of genotypic and phenotypic relation ship (pg. 192, column 1).

It would be obvious to one having the ordinary skill in the art at the time the invention was made to include the total DNA, RNA and protein component from the same sample of Riol in the nucleic acid and protein isolation method of Ibrahim with the expected benefit of using optimized method isolate total DNA, RNA and protein component from limited amount of biological materials simultaneously from the same sample to enhance the understanding of genotypic and phenotypic relation ship as taught by Riol (pg. 192, column 1).

Regarding claim 3, Ibrahim teaches the DNA and RNA are bound to distinct solid supports (column 8, lines 15-28).

Regarding claim 6, Ibrahim teaches the RNA is mRNA (column 6, lines 1-3).

Regarding claim 7, Ibrahim teaches the DNA from a sample (column 8, lines 15-28) and includes cells that contain DNA within the cell (column 7, lines 10-14) thus teaching DNA is genomic.

Regarding claim 8, Ibrahim teaches the purification of DNA or RNA from a sample (column 8, lines 15-28) thus teaching the isolation of total RNA and DNA.

Claims 9-10 are dependent on claim 1. Teachings of Ibrahim in view of Riol are described previously in this office action.

Riol teaches the isolation of total RNA and DNA (Fig. 5, see RNA and DNA, pg. 193, column 2, paragraph 2; limitation of claim 8) and protein component (Fig. 5, see proteins, pg. 194, column 1; limitation of claim 10) from the same sample. The teachings of Riol isolating total RNA and DNA component from the same sample (pg. 193, column 2, paragraph 2; limitation of claim 8) thus meets the limitation of isolating total nucleic acid component (limitation of claim 9). Riol also teaches an optimized method isolate total DNA, RNA and protein component from limited amount of biological materials simultaneously from the same sample to enhance the understanding of genotypic and phenotypic relation ship (pg. 192, column 1).

It would be obvious to one having the ordinary skill in the art at the time the invention was made to include the total DNA, RNA and protein component from the same sample of Riol in the nucleic acid and protein isolation method of Ibrahim with the expected benefit of using optimized method isolate total DNA, RNA and protein component from limited amount of biological materials simultaneously from the same sample to enhance the understanding of genotypic and phenotypic relation ship as taught by Riol (pg. 192, column 1).

Regarding claim 11, Ibrahim teaches the sample is an environmental or biological sample (column 1, lines 14-16).

Regarding claim 12, Ibrahim teaches prior to contacting a sample with sample collection assembly, that is solid supports and the sample is subjected to a lysis, that is a preliminary treatment step to free the nucleic acid and/or protein components from structures or entities in which they may be contained (column 8, lines 16-18).

Regarding claim 17, Ibrahim teaches the sample is not divided at any stages of the nucleic acid purification (column 8, lines 16-28).

Claim 18 is dependent on claim 12, which is dependent on claim 1. Teachings of Ibrahim in view of Riol regarding claim 1 are described previously in this office action.

Regarding claim 18, Ibrahim does not teach dividing cells. However dividing cells before lysis was known in the art at the time of the claimed invention as taught by Riol.

Riol teaches the isolation of lymphocyte population of cells from blood sample and further teaches lymphocytes are used for cell count for viability (pg. 193, column 2, paragraph 1) thus teaching sample is divided after cell isolation. It would be obvious to one having the ordinary skill in the art at the time the invention was made to divide sample for quality control test with the expected benefit of maintaining high quality of lymphocyte preparation from different blood samples as taught by Riol (pg. 192, column 2) thus providing an alternative resource of excellent quality of cells in the method of nucleic acid and protein isolation of Ibrahim.

Regarding claim 19, Ibrahim teaches that the sample is lysed and cellular contents are contacted with the probe on the solid supports simultaneously (Columns 8 and 9, Examples 1, 3 and 4).

Claim 20 is dependent on claim 19, which is dependent on claim 1. Teachings of Ibrahim in view of Riol regarding claim 1 are described previously in this office action.

Regarding claim 20, Ibrahim does not teach sequential isolation of RNA and DNA and protein. However sequential isolation of RNA and DNA and protein was known in the art at the time of the claimed invention as taught by Riol.

Riol teaches the that the in a first step RNA is isolated from lymphocyte sample, in a second step DNA is isolated from said sample and in a third step, protein is isolated from said sample (pgs. 193 and 194, column 2, paragraph 3 and column 1).

It would be obvious to one having the ordinary skill in the art at the time the invention was made to sequentially process RNA first and then DNA and protein as taught by Riol that following organic phase separation, RNA is in the aqueous phase, DNA in the inter phase and proteins in the organic phase (pg. 193, column 2, paragraph 2) with the expected benefit of utilizing precious biological limited samples to enhance the understanding of genotypic and phenotypic relationship as taught by Riol (pg. 192, column 1) thus improving the assay utilities of the nucleic acid protein isolation method of Ibrahim.

Regarding claims 22-24, Ibrahim teaches nucleic acid purification to isolate DNA RNA after lysing the sample in denaturing buffer, that is detergent (column 8, lines 16-18, limitation of claim 22), DNA and RNA is isolated in the presence of detergent with sample collection assembly simultaneously (Ibrahim refers sample collection assembly also as Wand; column 8, lines 16-28; limitation of claims 23 and 24).

Regarding claim 26, Ibrahim teaches that the protein is isolated using an appropriate binding partner/ligand carried by or attached to or capable of binding to a wand, i.e., a solid support (Example 3 and 4, column 8 and 9, lines 55-67 and 1-41).

Regarding claim 28, Ibrahim teaches that solid supports comprise particles (Fig. 2, element # 13b, column 5, lines 24-28).

Conclusion

12. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Narayan K. Bhat whose telephone number is (571)-272-5540. The examiner can normally be reached on 8.30 am to 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram R. Shukla can be reached on (571)-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

RAM R. SHUKLA, PH.D.
SUPERVISORY PATENT EXAMINER

Narayan K. Bhat Ph. D.

Examiner

Art Unit 1634